



December 14, 2023

MedHealth Medical Limited
Steven Jiang
General Manager
701/101, BLDG 24, Block B, Yuanshan Zone
Shangcun, Gongming
Shenzhen, Guangdong 518106
China

Re: K231801

Trade/Device Name: MedHealth DVT compression Devices MHH900S/MHH900E
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: June 1, 2023
Received: June 20, 2023

Dear Steven Jiang:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Eric E. Richardson -S



for Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K231801

Device Name

MedHealth DVT compression Devices MHH900S/MHH900E

Indications for Use (Describe)

MedHealth DVT Compression Devices MHH900S/MHH900E are intended to increase venous blood flow in at risk patients in order to help prevent deep vein thrombosis.

Type of Use (Select one or both, as applicable)



Prescription Use (Part 21 CFR 801 Subpart D)



Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR807.92 (a) (1)]

Nov 21,2023

2. Submitter's Information [21 CFR807.92 (a) (1)]

Name of Sponsor: MedHealth Medical Limited

Address: 701/101, BLDG 24, Block B, Yuanshan Zone, Shangcun, Gongming, Shenzhen, 518106, China

Contact Name: Steven Jiang

Telephone No.: +86-13502865807

Fax No.: +86-755-88210289

Email Address: steven.jiang@medhealth.com.cn

3. Trade Name, Common Name, Classification [21 CFR807.92 (a) (2)]

Trade Name/Model: MedHealth DVT compression Devices MHH900S/MHH900E

Common Name, MHH900S/MHH900E DVT Pumps

Classification Name: Sleeve, Limb, Compressible

Regulation Number: 21 CFR 870.5800

Product code: JOW

Classification Panel: Cardiovascular

Device Class: Class II

4. Identification of predicated Device (S) [21 CFR807.92 (a) (3)]

The predicate device is B&J Manufacturing Ltd. Deep Vein Thrombosis (DVT) compression device MHH800 (K200154)

5. Description of the Device [21 CFR807.92 (a) (4)]

The Deep Vein Thrombosis (DVT) Pumps MHH900S and MHH900E are external pneumatic compression (EPC) devices that aid in the prevention of DVT from a potentially life-threatening condition which can lead to pulmonary embolism. MHH900S and MHH900E are non-invasive mechanical prophylactic devices. The devices function as secondary

pumps to propel venous blood for patients whose deep vein thrombosis must be prevented after surgeries in Orthopedics etc. Additionally, the devices are reusable and can be used for more than one patient within its lifecycle.

The two devices separately consist of an air pump and a soft pliable compression garment(s) (Purchased separately) for the foot, calf, or thigh. For MHH900S and MHH900E, the controller supplies compression on a preset timing cycle (12 seconds inflation and maintenance followed by 48 seconds of deflation) at a suggested pressure setting of 40 mmHg for the Leg and 120mmHg for the Foot. The pressure in the garments is transferred to the extremity, augmenting venous blood flow when the leg is compressed, reducing stasis. This process also stimulates fibrinolysis; thus, reducing the risk of early clot formation.

The DVT pumps produce automatically timed cycles of compressed air. This compressed air forces blood out of the deep veins, helping to prevent slowed or stopped blood flow. Bursts of air are delivered to the specially designed garments wrapped around extremities. This air helps to move blood out of the deep veins and reduce the risk of developing DVT.

6. Intended Use [21 CFR807.92 (a) (5)]

MedHealth DVT Compression Devices MHH900S and MHH900E are intended to increase venous blood flow in at risk patients in order to help prevent deep vein thrombosis.

7. Technological Characteristics [21 CFR807.92 (a) (6)]**MHH900S DVT Pump**

General Specification:		
Model No.	MHH900S	
Size	8.6" (L) x 6.2" (W) x 8.98" (H)	
Weight	2.48 kg	
Pressure Range	Calf/Thigh Garment: 40mmHg +10/-5mmHg	
	Foot Garment: 120mmHg +10/-5mmHg	
Input Rating	AC 100V-240V 50/60Hz 1A	
Fuse Rating	1A or T1AH 250V	
Classification	Class I Type BF  Not AP or AGP type	
Humidity	Operation: 30% to 80 %	
	Storage & Transportation: 30% to 93%	
Air pressure	75 - 106KPA	
Temperature	Operation: 5° C- 40° C	
	Storage & Transportation: 5° C - 55° C	
Cycle Time	Inflation 12 seconds +/- 1second	
	Deflation 48 seconds +/- 2 seconds	
Applied Part	Garments (Purchased separately) and Air Tube	
Battery	Battery pack: 4 x series Li-ion battery cell	
	Battery pack capacity: 2900mAh (Nominal), 2700mAh (minimum)	
	Nominal voltage: 14.4V	
	Temperature: Operation 5°C ~ 40°C Storage 5°C ~ 55°C	
Garment for the DVT Pump (Purchased separately) :		
Model Name	Applied Part	Specification
801P	Calf	Small, for calf circumference up to 14" (35 cm)
801M	Calf	Medium, for calf circumference up to 18" (45 cm)
801L	Calf	Large, for calf circumference up to 24" (61 cm)
801B	Calf	Extra Large, for calf circumference up to 32" (81 cm)
820M	Foot	Medium, for foot sizes up to 13"
820L	Foot	Large, for foot sizes up to 16"
830S	Full-Leg	Small, for thigh circumference up to 22" (55 cm)
830M	Full-Leg	Medium, for thigh circumference up to 29" (73 cm)
830L	Full-Leg	Large, for thigh circumference up to 36" (91 cm)
830B	Full-Leg	Extra Large, for thigh circumference up to 42" (106 cm)
Air Hose Extension for the DVT Pump:		
810	Air hose extension of 59" (Pair)	
810L	Air hose extension of 118" (Pair)	

MHH900E DVT Pump

General Specification:		
Model No.	MHH900E	
Size	8.6" (L) x 6.2" (W) x 8.98" (H)	
Weight	2.48 kg	
Pressure Range	Calf/Thigh Garment: 40 mmHg +10/-5 mmHg	
	Foot Garment: 120 mmHg +10/-5 mmHg	
Input Rating	AC 100V-240V 50/60Hz 1A	
Fuse Rating	1A or T1AH 250V	
Classification	Class I Type BF  Not AP or AGP type	
Humidity	Operation: 30% to 80 %	
	Storage & Transportation: 30% to 93%	
Air pressure	75 - 106KPA	
Temperature	Operation: 5° C- 40° C	
	Storage & Transportation: 5° C - 55° C	
Cycle Time	Inflation 12 seconds +/- 1second	
	Deflation 48 seconds +/- 2 seconds	
Applied Part	Garments (Purchased separately) and Air Tub	
Battery	Battery pack: 4 x series Li-ion battery cell	
	Battery pack capacity: 2900mAh (Nominal), 2700mAh (minimum)	
	Nominal voltage: 14.4V	
	Temperature: Operation 5° C ~ 40° C Storage 5° C ~ 55° C	
Garment for the DVT Pump (Purchased separately) :		
Model Name	Applied Part	Specification
801P	Calf	Small, for calf circumference up to 14" (35 cm)
801M	Calf	Medium, for calf circumference up to 18" (45 cm)
801L	Calf	Large, for calf circumference up to 24" (61 cm)
801B	Calf	Extra Large, for calf circumference up to 32" (81 cm)
820M	Foot	Medium, for foot sizes up to 13"
820L	Foot	Large, for foot sizes up to 16"
830S	Full-Leg	Small, for thigh circumference up to 22" (55 cm)
830M	Full-Leg	Medium, for thigh circumference up to 29" (73 cm)
830L	Full-Leg	Large, for thigh circumference up to 36" (91 cm)
830B	Full-Leg	Extra Large, for thigh circumference up to 42" (106 cm)
Air Hose Extension for the DVT Pump:		
810	Air hose extension of 59" (Pair)	
810L	Air hose extension of 118" (Pair)	

8. Substantial Equivalence [21 CFR807.92 (a) (3) and 807.92]**8.1 Intended uses:****Table 1 Intended Use Comparison**

ID	Comparison Item	Proposed Device MedHealth DVT Compression Devices (MHH900S/MHH900E)	Predicate Device B&J DVT Compression Device (MHH800)
1	510(K) No.	To be assigned	K200154
2	Intended Use	The MedHealth Medical Limited. MHH900S and MHH900E Deep Vein Thrombosis (DVT) Compression Devices are intended to increase venous blood flow in at risk patients in order to help prevent deep vein thrombosis.	The B&J Manufacturing Ltd. MHH800 Deep Vein Thrombosis (DVT) Compression Devices are intended to increase venous blood flow in at risk patients in order to help prevent deep vein thrombosis.
3	Type of use	Prescription Use	Prescription Use
4	Single use	Reusable	Reusable

It is clear that the intended use of MHH900S and MHH900E is same as the predictive device MHH800

8.2 Comparison table**Table 2 General Comparison between MHH900S and MHH800**

ID	Comparison Item	Proposed Device MedHealth DVT Compression Device (MHH900S)	Predicate Device B&J DVT Compression Device (MHH800)	Explanation of Difference
5	General Specification			
5.1	Size	8.6"x6.2"x8.98"	6.5"x7.0"x12.8"	Different but does not raise any new issue of substantial equivalence

5.2	Weight	2.48kg	2. 1kg	Different but does not raise any new issue of substantial equivalence
5.3	Pressure Range	Calf/Thigh:40mmHg; Foot:120mmHg	Calf/Thigh:40mmHg; Foot:120mmHg	Same
5.4	Input Rating	AC 100-240V, 50/60Hz	AC 100-240V, 50/60Hz	Same
5.5	Fuse Rating	1A or T1AH 250V	1A or T1AH 250V	Same
5.6	Classification	Class I Type BF Not AP or AGP type 	Class I Type BF Not AP or AGP type 	Same

5.7	Operation Humidity	30-80%	30-75%	Different but does not raise any new issue of substantial equivalence
5.8	Storage & Transportation Humidity	30-93%	30-75%	Different but does not raise any new issue of substantial equivalence
5.9	Operation Temperature	5 ° C-40 ° C	15 ° C-35 ° C	Different but does not raise any new issue of substantial equivalence
5.10	Storage & Transportation Temperature	5 ° C-55 ° C	5 ° C-60 ° C	Different but does not raise any new issue of substantial equivalence
5.11	Applied Part	Garment(Purchased separately) and Air Hose	Garment(Purchased separately) and Air Hose	Same
5.12	Applied Mode of Pressure	Intermittent	Intermittent	Same
5.13	Number of Chambers in Garment	No	No	Same
5.14	Inflation chamber (Calf/Thigh)	12 seconds	12 seconds	Same
5.15	Deflation time per chamber (Calf/Thigh)	48 seconds	48 seconds	Same
5.16	Inflation time per chamber (Foot)	12 seconds	12 seconds	Same

5.17	Deflation time per chamber (Foot)	48 seconds	48seconds	Same
5.18	Pressure Range Calf/ Thigh	40mmHg	40mmHg	Same
5.19	Pressure Range Foot	120mmHg	120mmHg	Same
5.20	Pre- Programmed Controls	Yes	Yes	Same
5.21	Battery Pack	Yes	Yes	Same
5.22	Garments	Purchased separately, listed in 510(K) K201532 & K201547	Purchased separately, listed in 510(K) K201532 & K201547	Same
5.23	Contraindications for Use	● Severe congestive cardiac failure. ● Severe arteriosclerosis or other ischemic vascular disease. ● Extreme deformity of the limbs. ● Known or suspected deep vein thrombosis. ● Any local condition in which the garments would interfere: 1)Gangrene 2)Dermatitis 3)Untreated or infected wounds 4)Recent skin grafts	- Severe congestive cardiac failure. - Severe arteriosclerosis or other ischemic vascular disease. - Extreme deformity of the limbs. - Known or suspected deep vein thrombosis. - Any local condition in which the garments would interfere: - Gangrene - Dermatitis - Untreated or infected wounds - Recent skin grafts	Same

Table3 General Comparison between MHH900E and MHH800

ID	Comparison Item	Proposed Device MedHealth DVT Compression Device (MHH900E)	Predicate Device B&J DVT Compression Device (MHH800)	Explanation of Difference
5	General Specification			
5.1	Size	8.6"x6.2"x8.98"	6.5"x7.0"x12.8"	Different but does not raise any new issue of substantial equivalence
5.2	Weight	2.48kg	2.1kg	Different but does not raise any new issue of substantial equivalence
5.3	Pressure Range	Calf/Thigh:40mmHg; Foot:120mmHg	Calf/Thigh:40mmHg; Foot:120mmHg	Same
5.4	Input Rating	AC 100-240V, 50/60Hz	AC 100-240V, 50/60Hz	Same
5.5	Fuse Rating	1A or T1AH 250V	1A or T1AH 250V	Same
5.6	Classification	Class I Type BF Not AP or AGP type 	Class I Type BF Not AP or AGP type 	Same

5.7	Operation Humidity	30-80%	30-75%	Different but does not raise any new issue of substantial equivalence
5.8	Storage & Transportation Humidity	30-93%	30-75%	Different but does not raise any new issue of substantial equivalence
5.9	Operation Temperature	5 ° C- 4 0 ° C	1 5 ° C- 3 5 ° C	Different but does not raise any new issue of substantial equivalence
5.10	Storage & Transportation Temperature	5 ° C- 5 5 ° C	5 ° C- 6 0 ° C	Different but does not raise any new issue of substantial equivalence
5.11	Applied Part	Garment and Air Hose	Garment and Air Hose	Same
5.12	Applied Mode of Pressure	Intermittent	Intermittent	Same
5.13	Number of Chambers in Garment	No	No	Same
5.14	Inflation time per chamber (Calf/Thigh)	12 seconds	12 seconds	Same
5.15	Deflation time per chamber (Calf/Thigh)	48 seconds	48 seconds	Same
5.16	Inflation time per chamber (Foot)	12 seconds	12 seconds	Same

5.17	Deflation time per chamber (Foot)	48 seconds	48seconds	Same
5.18	Pressure Range Calf/ Thigh	40mmHg	40mmHg	Same
5.19	Pressure Range Foot	120mmHg	120mmHg	Same
5.20	Pre- Programmed Controls	Yes	Yes	Same
5.21	Battery Pack	Yes	Yes	Same
5.22	Garments	Purchased separately, listed in 510(K) K201532 & K201547	Purchased separately, listed in 510(K) K201532 & K201547	Same
5.23	Contraindications for Use	● Severe congestive cardiac failure. ● Severe arteriosclerosis or other ischemic vascular disease. ● Extreme deformity of the limbs. ● Known or suspected deep vein thrombosis. ● Any local condition in which the garments would interfere: ● Gangrene ● Dermatitis ● Untreated or infected wounds ● Recent skin grafts	- Severe congestive cardiac failure. - Severe arteriosclerosis or other ischemic vascular disease. - Extreme deformity of the limbs. - Known or suspected deep vein thrombosis. - Any local condition in which the garments would interfere: - Gangrene - Dermatitis - Untreated or infected wounds - Recent skin grafts	Same

It is cleared that the technological characteristics differences discussed above do not affect the safety and the effectiveness of the MHH900S and MHH900E

8.3 Non-clinical testing [21 CFR 807.92(b) (1)]

The following safety and performance test were conducted to assess MHH900S and MHH900E DVT compression Devices.

- Software validation
- Cleaning and Disinfection validation—Testing was performed to, and passed, the following standards:
 - AAMI TIR12: 2020 Designing, Testing And Labeling Reusable Medical Devices For Reprocessing In Health Care Facilities: A Guide For Medical Device Manufacturers
 - ASTM F3208-20 Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices
 - AAMI ST98-2022 Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical device
- Electromagnetic compatibility and electrical safety-- testing was performed to, and passed, the following standards:
 - IEC 60601-1 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
 - IEC 60601-1-2 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility –Requirements and tests
 - IEC 60601-1-8 Medical electrical equipment –Part 1-8: General requirements for basic safety and essential performance –Collateral standard: General Requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
 - IEC TR 60601-4-2:2016 Medical electrical equipment –Part 4-2: Guidance and interpretation Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- Shelf life (aging test)—Follow ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Device
- Performance test summary:

Testing was performed and to ensure that the system meets its specifications. The manufacturer believes that the technological characteristics of the MHH900H & MHH900S are substantially equivalent to primary predicate and reference device. The functional performance testing includes the following tests:

 - Pressure accuracy Range-Calf/Thigh Garment
 - Pressure accuracy Range- Foot Garment
 - Cycle Time-Inflation
 - Cycle Time-Deflation
 - Burst Testing
 - Pressure Leakage testing

No clinical testing was used to support the decision of safety and effectiveness.

9. Conclusion [21 CFR 807.92(b) (3)]

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and base on the information provided in this premarket notification, MedHealth Medical Limited concludes that:

The intended use of MHH900S and MHH900E are the same as that of the predicate devices. Demonstrated by the safety and performance tests, the MHH900S/MHH900E are as safe and as effective as the predicate device and therefore are substantially equivalent to the predicate device.